K023591

JUN 18 2003

DeRoyal Industries, Inc.

Ultra High Pressure Injector Lines

510(k) Summary

Summary of the Safety and Effectiveness Information
Upon Which
An Equivalence Determination Could Be Based

SUBMITTER INFORMATION:

NAME:	DeRoyal Industries, Inc.	**TELEPHONE:**	(865) 362-6157
ADDRESS:	200 DeBusk Lane	**CONTACT:**	Sharon Cook
	Powell, TN 37849	**DATE OF PREPARATION:**	March 20, 2003

DEVICE NAMES

Name: **Ultra High Pressure Injector Lines**
COMMON/USUAL NAME: Pressure Line
CLASSIFICATION NAME: DQO, Percutaneous Catheter
Class II device per 21 CFR 870.1250

PREDICATE OR LEGALLY MARKETED DEVICES

NAMIC - flexCIL® Contrast Injection Lines (K822100)
Maxxim Medical Inc. – High Pressure Lines (K963749)

DEVICE DESCRIPTION

The DeRoyal Industries, Inc. Ultra High Pressure Injector Lines are comprised of PVC tubing ranging in length from 10" to 48". These devices have been tested to withstand up to 3 injections with a limiting pressure of 1200 psi.

Device Design/Materials Used/Physical Properties: The DeRoyal Industries, Inc. Ultra High Pressure Injector Lines are made of PVC material commonly used in the industry for their purpose.

DEVICE INTENDED USE

The DeRoyal Industries, Inc., Ultra High Pressure Injector Lines are indicated for use during coronary angiography procedures as a connecting line for the injection of radio-opaque dye or saline.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICES

Characteristic	DeRoyal Device	Other Devices
Material	Plastic Polymers	Plastic Polymers
Flexible	Yes	Yes
Sterility	Sterile and Non-Sterile	Sterile and Non-Sterile
Disposable	Yes	Yes
Package	Bulk, single put-ups or as a component in trays or kits	Bulk, single put ups or as a component in trays or kits
Disposable	Yes	Yes
Pressure Rating	1200 psi	1200 psi

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2003

Ms. Sharon Cook
Regulatory Affairs Group Manager
DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849

Re: K023591
Ultra High Pressure Injector Lines
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: March 20, 2003
Received: March 24, 2003

Dear Ms. Cook:

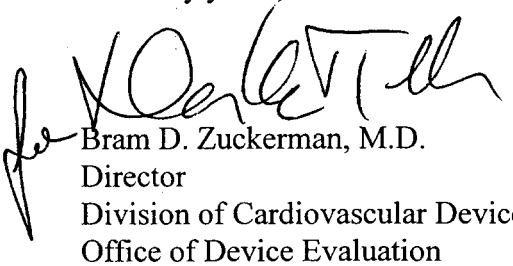
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 11

INDICATIONS FOR USE STATEMENT

Applicant: DeRoyal Industries, Inc.

510(k) Number (if known): K023591

Device Name: Ultra High Pressure Injector Lines

- **Indications for Use:**

The DeRoyal Industries, Inc., Ultra High Pressure Injector Lines are indicated for use during coronary angiography procedures as a connecting line for the injection of radio-opaque dye or saline.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023591